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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,874	08/22/2003	Timothy J. Miller	15463ZYXWV (PC9003E)	6784

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,874

Applicant(s)

MILLER ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,13,23,28,29,31,36,38,44,46 and 49-56 is/are pending in the application.
- 4a) Of the above claim(s) 13,23,28,29,31,36,38,44,46 and 49-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/28/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, with peptide residues 137- 151, in the reply filed on 14 June 2004 is acknowledged. The traversal is on the ground(s) that the inventions are drawn to common subject matter, that classification is not a good method to show patentable distinctness, and that all inventions should be searched because they are are not independent and distinct. This is not found persuasive because peptides, antibodies, and nucleic acids are different structures and each requires a different search, methods using the different products are different from each other, and the methods can be practiced with different products.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13,23,28,29,31,36,38,44,46 and 49-56 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1-4 and 6-10.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 6/28/04 is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, and 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for residues consisting of residues 137-151 of WT DF2/WT WSU 1146 for diagnostic uses of differentiating FIPV from FECV, does not reasonably provide enablement for peptides comprising residues 137-151, methods of treatment or prophylaxis using any peptides, or peptides from other related viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The invention is drawn to protein that can be useful to diagnose, treat, or prophylaxis for a disease caused by a coronavirus.

Specification provides guidance and direction to use only residues 137-151 to differentiate certain FIPV strains from FECV (Table VI). From the control in Table VI and the NT result in Table V (which does not show the other peptide will react the same way

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as 137-151). Even though Example 13 is called Challenge Studies, all that is done is make antibodies, there is no showing that a protective response is raised or that there is a therapeutic effect if used as a treatment if a peptide or protein has been used.

There are no additional working examples that show other peptides from other viruses that can be used.

The specification does not teach how to differentiate SARS caused by coronaviruses or other related viruses or diseases caused by them.

It is not shown what sequences can be added to the peptide 137-151 to be still useful. It cannot be determined what sequences comprising 137-151 will be able to differentiate between FIPV and FECV because additional epitopes will be added and it is not known if they will have the same properties or if they will function in the same manner.

The enabling disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed invention. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs *et al.* (from IDS, Virus Research 1987, 8:363).

The claims are drawn to an S protein from a coronavirus or related virus that is useful in diagnosis.

Jacobs *et al.* teach an S protein from FIPV and a related virus TGEV (Figure 2a and 2b).

The divergent region in the N terminal region of the two proteins would be useful in differentiating the two viruses.

Thus, Jacobs *et al.* anticipate the claimed invention.

Double Patenting

Claims 1-4 and 6-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. US006642359B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to identical peptides of residues 137-151 of identical SEQ ID#s. The patent (parent of this application) claims positions 137-151 of SEQ ID#32 and the instant claims read on that sequence as well.

Conclusion

No claim is allowed.

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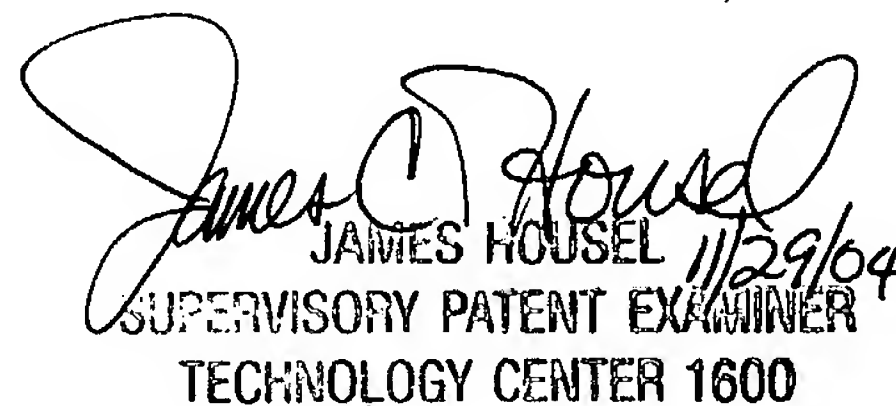
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
November 22, 2004



JAMES HOUSEL 11/29/04
SUPERVISORY PATENT EXAMINER
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